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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,487	10/28/2005	Mitsuo Fukuda	9694D-000014/US	6301
30593 7590 04/28/2009 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195			EXAMINER RANADE, DIVA	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 04/28/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,487	Applicant(s) FUKUDA ET AL.	
	Examiner DIVA RANADE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/08, 7/13/07, 5/2/07, 6/22/06, 5/16/05, 2/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Priority

1. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. For the purposes of this examination Examiner will use 12/16/04 for priority.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

Art Unit: 3763

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 7, 17, 18, 32, and 33 are rejected on the ground of nonstatutory double patenting over claims 1, 7, 10, 11, 12, 14, 16-19, 23, and 26 of U. S. Patent No. 7,361,182 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The elements of claims 1, 7, 10, 11, 12, 14, 16-19, 23, and 26 can be found in the claims 1, 7, 10, 11, 12, 14, 16-19, 23, and 26 of U.S. Patent No.

Art Unit: 3763

7,361,182. The difference between the claims of the application and claims of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the patent is in effect a "species" of the "generic" invention of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir 1993).

Since the claims of the application are anticipated by the claims of the patent, they are not patentably distinct from the claims of the application. It would be obvious to modify the claims of the patent in order to broaden the claims of the application.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 7, 9, 10, 12, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,766,163 to Mueller et al.

a. Claim 1, 2, 7, 9, 10, 12, 32 and 33: Mueller shows a medical device (Fig 4A) with a sharp tip (Fig 4C) where a plurality of maximal point where the cross-sectional area of the vertical cross-section is locally maximal and a plurality of minimal points where the cross-sectional area of the

Art Unit: 3763

vertical cross section is locally minimal and the cross-section at the maximal point closest to the tip has a cross sectional area not less than those at any other maximal points as in claims 1 and 32. The vertical cross section is shaped as a circle as in claim 7 and the minimal points have the same cross sectional area as each other as in claim 9. The cross section at a minimal point closer to the needle tip has a cross sectional area less than that at a maximal point closer to the rear end as in claim 10. As can be seen from Fig. 4A the distance between a pair of the adjacent maximal points is substantially equal to one between another pair of adjacent maximal points as in claim 12. When viewed on a projected plane parallel to the predetermined direction, the cross sectional area varies in a curved manner between one of maximal points and the adjacent one of the minimal points as in claim 33 (See Fig 4A).

Furthermore there is a channel having at least one opening which is extended along a predetermined direction as in claim 2.

b. Claim 15: Mueller does not discuss a radius of curvature at the sharp tip. However, at the tip the radius of curvature varies at each vertical cross section. At some position the tip is capable of having a radius of curvature at 10 um or less.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

Art Unit: 3763

be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,766,163 to Mueller et al.

c. Claim 3: Mueller shows does not show a chamber in communication with the channel but does shows a suture apparatus attached to the device in communication with the needle tip. It would be obvious to one skilled in the art during the time of the invention to include a drug delivering chamber in the place of the suture apparatus in order to deliver a therapeutic substance to the area of concern.

10. Claims 4, 5, 14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,766,163 to Mueller et al in view of U.S Patent 6,673,058 to Snow.

d. Claims 4, 14 and 16-18: Mueller shows a sharp tip (Fig 4C) but does not show the groove or slit of claims 4 and 16, the grating of claim 14 or that the needle is made of a biocompatible of biodegradable device as in claims 17 and 18. Snow shows a tip with a groove or slit (Fig 5A-DE) or grating (Fig 6F) attached to a biocompatible body (See Column 2 lines 65-66) whereas the tip is completely biodegradable (See Column 5 lines 7-16). It would be obvious to one skilled in the art during the time of the invention to modify the tip of Mueller with the tip of Snow in order to provide a groove or slit for better communication of the fluid to the area of

Art Unit: 3763

concern. Furthermore, the material of Snow can be used to construct the device of Mueller.

e. Claim 5: Mueller shows does not show a chamber in communication with the groove but does shows a suture apparatus attached to the device in communication with the needle tip. Snow shows a groove in the tip (See Fig 5A to 5E). It would be obvious to one skilled in the art during the time of the invention to include a drug delivering chamber in the place of the suture apparatus in the modified device of Mueller and Snow in order to deliver a therapeutic substance to the area of concern.

11. Claims 6, 8, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,766,163 to Mueller et al in view of U.S. Patent 7,445,616.

f. Claims 6, 8, 11 and 13: Mueller does not show that the maximal point closer to the tip has a cross-sectional greater than that at another maximal point closer to the needle rear or that the a minimal point closer to the rear is less that any other minimal point or that the maximal points closer to the tip is more spaced apart than another pair of adjacent maximal points. Finally, Mueller does not show that the cross section varies in a linear manner between one of the maximal points and an adjacent minimal point. Petrakis shows a drug delivery device which includes the above elements as well as the elements of Mueller in other embodiments. Therefore it would be obvious to one skilled in the art

Art Unit: 3763

during the time of the invention to vary the shape of the body and tip of Mueller with that of Petrakis in order to provide a variety of options for drug delivery such as leaving the device within the tissue when the edges are varied in a linear manner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIVA RANADE whose telephone number is (571)270-7456. The examiner can normally be reached on M-F, 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 3763

/DIVA RANADE/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763